



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Kathleen D. Danenberg  
Group Art Unit: 1637  
Application No.: 09/998,333  
Filed: December 3, 2001  
Docket No.: 11220/146  
Examiner: Jeffrey Siew  
For: METHOD OF DETERMINING A CHEMOTHERAPEUTIC  
REGIMEN BY ASSAYING GENE EXPRESSION IN PRIMARY  
TUMORS

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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Sir:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). The paragraphs marked below are applicable. It is believed that no fees other than those indicated below are due, but authorization is hereby given to charge any additional fees due, or to credit any overpayment, to deposit account 11-0600.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
U.S. Application Serial No. 09/998,333

☐ 1. This Information Disclosure Statement is being filed (a) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53(d), (b) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, (c) before the mailing date of a first Office Action on the merits in the present application, OR (d) before the mailing of a first office action after filing of a request for continued examination. No certification or fee is required.

☒ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a final action, Notice of Allowance, or any action that otherwise closes prosecution.

☒ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).

☐ c. Please debit Deposit Account No. 11-0600 in the amount of \$180.00 in payment of the fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 CFR §1.97(c)(2). Respectfully submitted,

KENYON & KENYON

Date: 10/03/03

  
Teresa A. Lavenue  
Registration No. 47,737

Customer No. 23838

1500 K Street, NW - Suite 700  
Washington, DC 20005  
(202) 220-4200  
(202) 220-4201 (fax)  
DC470360v1



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PTO FORM 1449**

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**11220/146**

SERIAL NO.  
**09/998,333**

APPLICANTS  
**Kathleen D. DANENBERG**

FILING DATE  
**December 3, 2001**

GROUP  
**1637**

**U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	PATENT/PUBLICATION NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE
	5,952,202	September 14, 1999	Aoyagi et al.			

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

**OTHER DOCUMENTS**

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Aschele, C., et al., "Thymidylate Synthase Protein Expression in Primary Colorectal Cancer Compared with the Corresponding Distant Metastases and Relationship with the Clinical Response to 5-Fluorouracil," Clinical Cancer Research, 6: 4797-4802 (2000)
	Chen, Z., et al., "Correlation of Cisplatin Sensitivity with Differential Alteration of EGFR Expression in Head and Neck Cancer Cells," Anticancer Research 20:899-902 (2000)
	Etienne M.C., et al., "Response to Fluorouracil Therapy in Cancer Patients: The Role of Tumoral Dihydropyrimidine Dehydrogenase Activity," Journal of Clinical Oncology, 13(7):1663-1670 (1995)
	Beck, A., et al., "A Role for Dihydropyrimidine Dehydrogenase and Thymidylate Synthase in Tumour Sensitivity to Fluorouracil," European Journal of Cancer, 30A(10):1517-1522 (1994)
	Gorlick, R., et al., "Higher Levels of Thymidylate Synthase Gene Expression Are Observed in Pulmonary as Compared With Hepatic Metastases of Colorectal Adenocarcinoma," Journal of Clinical Oncology, 16(4):1465-1469 (1998)
	Kornmann M. et al., "Thymidylate synthase is a predictor for response and resistance in hepatic artery infusion chemotherapy," Cancer Letters, 118:29-35 (1997)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT PTO FORM 1449</b>  Page 2/2	ATTY. DOCKET NO. <b>11220/146</b>	SERIAL NO. <b>09/998,333</b>
	APPLICANTS <b>Kathleen D. DANENBERG</b>	
	FILING DATE <b>December 3, 2001</b>	GROUP <b>1637</b>

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Lenz, H.-J., <i>et al.</i> , "p53 Point Mutations and Thymidylate Synthase Messenger RNA Levels in Disseminated Colorectal Cancer: An Analysis of Response and Survival," Clinical Cancer Research, 4:1243-1250 (1998)
	Neskovic-Konstantinovic, Z., <i>et al.</i> , "Expression of Epidermal Growth Factor Receptor in Breast Cancer, from Early Stages to Advanced Disease," J. Exp. Clin. Cancer Res., 18(3):347-355 (1999)
	Newby J.C., <i>et al.</i> , "Expression of Epidermal Growth Factor Receptor and c-erbB2 during the Development of Tamoxifen Resistance in Human Breast Cancer," Clinical Cancer Research, 3:1643-1651 (1997)
	Nicholson, R.I., <i>et al.</i> , "Relationship Between EGF-R, c-erbB-2 Protein Expression and Ki67 Immunostaining in Breast Cancer and Hormone Sensitivity," Eur. J. Cancer, 29A(7):1018-1023 (1993)
	Salonga D., <i>et al.</i> , "Colorectal Tumors Responding to 5-Fluorouracil Have Low Gene Expression Levels of Dihydropyrimidine Dehydrogenase, Thymidylate Synthase, and Thymidine Phosphorylase," Clinical Cancer Research 6:1322-1327 (2000)
	Wong, NACS, <i>et al.</i> , "Nuclear thymidylate synthase expression, p53 expression and 5FU response in colorectal carcinoma," British Journal of Cancer, 85(12):1937-1943 (2001)
	Yamada, H., <i>et al.</i> , "Thymidylate Synthase Gene Expression in Primary Colorectal Cancer and Metastatic Sites," Clinical Colorectal Cancer, 1(3):169-173 (2001); discussion p. 174

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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